

### **REMARKS**

Claims 21, 27-32, and 35-36 constitute the pending claims in the present application. Claims 22-26, and 33-34 have been canceled. Claims 21, 27-32, and 35-36 are under examination. Claims 21, 35, and 36 have been amended in response to the Office Action. Claims 29-31 have been amended to correct obvious errors. Claim 37 has been added. Support for these amendments and new claim 37 can be found, for example, in examples 6-9 on pp. 15-18, and p. 8, line 4 to p. 12, line 15 of the original specification as filed. No new matter has been introduced by these amendments. Applicants respectfully request reconsideration of the previous rejection in view of the foregoing amendments and following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

Restriction: The Examiner has maintained his restriction of the current invention to Groups I-II. Applicants previously elected Group I with traverse. The Examiner recommends that the applicants cancel the non-elected subject matter. While the applicants disagree with the Examiner's restriction, the subject matter of Group II in former claims 21, 22-26 and 33-34 has been canceled solely to expedite prosecution of the application.

Rejection Based on 35 U.S.C. 112: Claim 36 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Applicants traverse this rejection to the extent that it is maintained over the claims as amended.

The Examiner contends that the subject matter was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. The Examiner further states that the scope of the claims is not adequately enabled based on the in vitro testing provided in the specification and that there is nothing in the disclosure regarding how this in vitro data correlates to the treatment or prevention of vascular disease or diseases related to vascular disorders. Specifically, the Examiner objects to the term "preventing" in claim 36 and alleges that the only thing available is the treatment of some type of vascular diseases, but not the prevention of getting vascular disease in the first place.

Although Applicants assert that the prevention of vascular diseases is fully supported by the specification, Applicants have amended claim 36 to no longer recite "prevention". In addition, while Applicants assert that the treatment of diseases related to vascular disorders,

solely to expedite prosecution, Applicants have amended claim 36 to no longer recite "diseases related to vascular disorders".

With regard to the enablement rejection of the treatment of vascular diseases, the Examiner acknowledges that vascular disease is mainly caused by atherosclerosis, a condition leading to narrow, hardened arteries so that there is insufficient blood flow to satisfy the needs of a tissue. Relaxing the blood vessels stricken with atherosclerosis, allowing a widening of the blood passageway is helpful to improve blood flow, alleviating symptoms accompanying restricted blood flow. The class of compounds of the invention claimed herein does just that: relax the blood vessels. The scope of the claims is not defined by the cause of vascular diseases, but the treatment, which has the effect of dilating the blood vessels. The examples given in the specification clearly support this effect. Therefore, Applicants respectfully submit that, the indications of claim 36 as amended are supported by the examples provided in the specification.

Rejection Based on 35 U.S.C. 112: Claims 35-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In item a, the Examiner states that claim 35 is rejected because the pharmaceutical composition lacks a carrier. Although Applicants assert that "a pharmaceutical composition" without a carrier is clear and unambiguous to one skilled in the art, Applicants have amended claim 35 to read, "A pharmaceutical composition comprising a compound of formula III as defined in claim 21 and a pharmaceutically acceptable carrier."

### **Specification**

The Examiner objects to the term "Dragées" asserting that this term is not part of the English language. Applicants traverse this rejection. In the American Heritage College Dictionary of the English Language: Fourth Edition, the term Dragée is defined as "a, small, often medicated candy." The plural of this term is "dragées". Applicants respectfully request reconsideration of the above objections to the specification based on Applicants amendments and remarks. (See Exhibit A).

The Examiner objects to the term "q. s. ad." at pages 24-25 asserting that it is unclear what the term stands for. Applicants respectfully submit that "q. s. ad." is a pharmaceutical abbreviation used in formulations. The abbreviation stands for the Latin term "quantum sufficiat ad". This term translates to English as "a sufficient quantity to make". Therefore, when taken in the context that it is printed, the term describes combining the 2 mg of the referenced compound (N-[2-chloro-3-(1-piperidinyl)propoxy]-pyridin-1-oxide-3-carboxamide methanesulfonate) and diluting to 2 mL to make the injectable solution. (See Exhibit B).

The Examiner also objects to the term "pyrogen-free" at pages 24-25 asserting that it is unclear what the term is. Applicants respectfully submit that a "pyrogen" is a fever producing substance such as bacteria. (See Exhibit C). The "sterile, pyrogen-free" terminology is often used when referring to biological solutions such as saline. Applicants respectfully request reconsideration of the above objections to the specification based on Applicants remarks.

### **Objection**

The Examiner objects to claims 21, and 27-32 and states that they would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

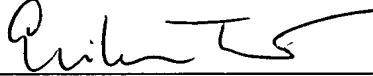
Applicants respectfully submit that claim 21 is already correctly formatted as an independent claim. In addition, Applicants submit that claims 27-32 are correctly formatted as dependent on claim 21. Per our June 27, 2007 telephone conversation with Examiner Habte, Applicants will not respond further to this objection.

**Conclusion**

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 212.596.9000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to Deposit Account No. 18-1945, under Order No. 004049-0022 from which the undersigned is authorized to draw.

Dated: July 30, 2007

Respectfully submitted,

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